REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the remarks that follow.

I. Claim Status

Claims 1-25 are cancelled presently, without prejudice or disclaimer, and claims 26-333 are added. No claims are amended.

Support for the added claims is evident throughout the specification. Thus, support for new claims 26-27 can be found on page 4, line 16 – page 6, line 28 and page 7, line 21 – page 10, line 5, support for new claim 28 can be found on page 4, line 32 – page 5, line 1, support for new claim 29 can be found on page 4, lines 5-7, support for new claim 30 can be found on page 5, lines 1-3, page 7, lines 28-32 and page 13, line 1 – page 31, line 5, support for new claim 31 can be found on page 27, line 3 – page 28, line 35 and Figure 15 and support for new claims 32-33 can be found on page 6, lines 17-23.

From the foregoing it is apparent that the above-discussed changes introduce no impermissible new matter and, hence, that entry of the changes is appropriate. Upon such entry, claims 26-33 will be pending and subject to examination on the merits.

II. Section 112 Rejections Should Be Withdrawn

Claim 21 is rejected for alleged indefiniteness, and claims 20-22 are rejected for an asserted lack of written-description support in the specification. The present cancellation of claims 20-22 renders these rejections moot, however.

III. Section 102 Rejections To Claims 19-25 Should Be Withdrawn

Claims 19-25 stand rejected for alleged anticipation by Sair, U.S. 4,230,687, as evidenced by Wheat Flour (http://en.wikipedia.org/wiki/Flour). The present cancelation of claims 19-25 renders this rejection moot, too.

IV. New Claims 26-33 Are Patentable

The various grounds for rejection, lodged against the canceled claims, are inapposite to the present claims, including independent claim 26. Claim 26 is directed to a material for encapsulating a therapeutic and nutritional agent, which is storage unstable.

The material of claim 26 is produced by a process that includes the steps of "treating a starch to increase the number of sugar reducing groups in the resulting treated starch;" and then "forming a dispersion of a film forming protein and the treated starch in an aqueous phase." The forming step is followed by "mixing the agent with the dispersion to form a mixture" and then "homogenizing the mixture to obtain an emulsion, such that the treated starch and the film forming protein form a protective shell around the agent during the homogenizing step, which shell allows release of the agent in the gastrointestinal tract."

This methodology ensures that the mixture is homogenized to obtain an emulsion. Specification at page 6, lines 24-26. The emulsion protects the agent against early uptake and metabolism in the stomach and upper gastrointestinal (GI) tract. *Id.* at page 3, line 28 – page 6, line 28. If the agent, film forming protein, and treated starch are not so homogenized, then the treated starch and film forming protein do not form a protective shell around the agent. *Id.* Such a failure results in release of agent before it reaches the GI tract, thereby preventing the delivery there of essential components. *Id.* at page 1, lines 23-29.

The examiner relies on Sair to disclose "an encapsulation material forming [a] protective matrix to encase vitamins (lipids) in order to prevent minimizing oxidation and controlling release of vitamins (lipids)." Office Action at page 5. While acknowledging that Sair's method is not the same as the method now recited (*Id.* at pages 5-6), the examiner contends that the "encapsulation material disclosed by Sair et al. comprises the same components as the encapsulation material recited in the instant claim [and] thus [the] encapsulation material disclosed by Sair et al. would necessarily posses the same release property as that of the encapsulation material" of the claimed invention. *Id.* at page 6.

In fact, Sair discloses that "[s]ome processes call for forming solutions or aqueous emulsions of the agent to be encapsulated," but that the "process [taught by the reference] facilitates encapsulation, utilizing a relatively simple procedure in which the water concentration is controlled." Column 1, lines 27-30, and column 2, lines 3-5. Sair also discloses that a "related feature of the

[disclosed] invention is that a markedly reduced concentration of water is possible, thus effecting material savings in the energy normally required to dispel moisture from the final product." *Id.* at column 2, lines 28-31. Sair further teaches that the "quantity of water should only be sufficient to produce a viscous paste with the encapsulating material," because exposing starches to increased concentrations of water will cause "the resulting product [to be] much more fluid, and it becomes extremely difficult to form the desired sheet." *Id.* at column 4, lines 2-13, and at column 4, lined 60 – column 5, line 11.

Pursuant to Sair's method, therefore, very little water is used in the encapsulating process, which means that no emulsion is formed thereby. Accordingly, Sair actually teaches away from homogenizing a mixed agent, film forming protein, and treated starch to obtain an emulsion, as presently recited. To the contrary, Sair explicitly states that his method "differs markedly from prior art encasement or encapsulation techniques which utilize … ***emulsions***," *inter alia*. *Id.* at column 9, lines 8-11 (emphasis added).

Thus, Sair employs a process that does not involve a "homogenizing" and cannot yield an "emulsion," *contra* applicants' claimed invention. It necessarily follows that Sair does not teach, explicitly or inherently, a material characterized by the presence of "a protective shell" structure, as presently recited, which protects an otherwise storage-unstable "agent" in order that the latter can be "release[d] … in the gastrointestinal tract," as applicants' invention allows. Claim 26 and its dependents should be deemed patentable, therefore, over the prior art represented by Sair.

Claim 27 is allowable as well by virtue of its reciting a "further" step of "spray drying the emulsion" discussed above. To the contrary, Sair's methodology is said to "differ[] markedly from prior art encasement or encapsulation techniques which utilize … ***spray drying procedures***." Column 9, lines 8-11 (emphasis added). That Sair eschews such spray drying also is apparent from his teaching of a procedure "in which the water concentration is controlled," such that the "quantity of water [is] only sufficient to produce a viscous paste." *Id.* at column 2, lines 3-5, and at column 3, line 67 – column 4, line 5. Thus, Sair teaches using only enough water to produce a viscous paste, which is not amenable to a spray-drying procedure.

CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Yu also is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

Date May 10, 2011

By /Stephen A. Bent/

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.